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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,445	11/29/2001	Lexun Xue	2896-4005	3445
27123	7590	10/12/2005	EXAMINER	
MORGAN & FINNEGAN, L.L.P.			HELMER, GEORGIA L	
3 WORLD FINANCIAL CENTER			ART UNIT	
NEW YORK, NY 10281-2101			PAPER NUMBER	

1638

DATE MAILED: 10/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,445

Applicant(s)

XUE ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,7,9 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,7,9 and 12-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>No 66</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 March 2005 has been entered.

Status of the Claims

2. Claims 1, 6, 12 and 14 have been amended. Claims 1, 6, 7, 9, and 12-14 are pending, and are examined in the instant action.
3. All rejections not addressed below have been withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The 3 March 2005 submission of a document listing TNF-related DNA and protein sequence is acknowledged. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 112, first paragraph

Written description

6. Claims 1, 6, and claims 7, 9, 12, and 14 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 is drawn to a transgenic *Dunaliella Salina* bioreactor comprising ... hepatitis B surface antigen (HBsAg) (line 6)..

Claim 6 is drawn to a method of preparing a transgenic *Dunaliella Salina* bioreactor, comprising ...(a) line 4-5, "hepatitis surface antigen gene".

Claim 12 is drawn to the method ..consisting of ..HBsAg gene....

Claim 14 is drawn to the method of claim 12 where the target gene is HBsAg comprising the steps

(a) amplifying a SS1 fusion gene comprising the fusion of a gene encoding amino acid residues 1-226 of HBsAg and a PreS1 gene encoding amino acid residues 20-48 of PreS1 of hepatitis B viral gene and ligating the fusion gene at Sall/SphI site;

However the specification does not disclose to what the numbers of "gene encoding amino acid residues 1-226 of HBsAg and a PreS1 gene encoding amino acid

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residues 20-48 of PreS1 of hepatitis B viral gene" refer. No frame of reference is given for these numbers. The specification at Example 2(p. 13, line 17 bridging p. 14, line 5) discusses the construction of the recombinant HBsAg fusion gene, giving the same description information as in claim 14, with no further information or data.

Applicant is encouraged to submit information re the HBsAg being well known to one skilled in the art as of the time of filing.

The TNF information in the specification fulfills the written description requirement, since TNF is well known in the art.

Claim Rejections - 35 USC § 112 Enablement

7. Claim 1, 6, 7, 9, 12 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's claims are drawn to polynucleotide and amino acid sequences which are not appropriately described to fulfill the 112.1 Written Description requirement, and would not have been in possession of the genus claimed at the time this application. Since the claimed invention lacks written description, it would not be possible for one skilled in the art to make and use the invention.

The claims are drawn to a method for preparing transgenic *Dunaliella Salina* by a foreign target gene selected from the group of TNF and HBsAg together with a selectable marker consisting of *aadA* gene, and a BAR gene, as well as claims drawn to a transgenic *Dunaliella Salina* bioreactor made by the method.

Applicant's Example I describes the construction of an expression vector comprising a *Dunaliella Salina* chloroplast promoter and the human TNF α and a (Specification, p. 10 line 9 bridging to p. 11 line 11), followed by introduction of this DNA into *Dunaliella Salina* cells via electroporation (specification, p. 11, lines 13-29).

Applicant's Example II describes construction of an expression vector comprising a *Dunaliella Salina* Hsp70B 5' promoter and a hepatitis B antigen gene fusion with cholera toxin B (Specification, p. 14 line 6 bridging to p. 15 line 12), followed by introduction of this DNA into *Dunaliella Salina* cells via electroporation (specification, p. 11, line 13-29). Applicant does not describe the production of transgenic *Dunaliella Salina*, which function as a bioreactor. What experiment was done that results in the production of transgenic *Dunaliella Salina*, which function as a bioreactor?

The Examiner is unable to glean the specifics of what "worked" and by what method (assay) was that "working" determined to be successful. In the interview of 24 June 2005, a copy of which is enclosed, this matter was discussed in some detail.

Applicant is invited to provide additional relevant information in the form of a §132 Declaration by the inventor or other appropriate person.

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Remarks

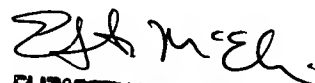
8. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on M-Th, 10:30am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 571-272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer
Patent Examiner
Art Unit 1638
September 30, 2005


ELIZABETH MCELMAN
PRIMARY EXAMINER